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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,182	06/11/2001	Daniel C. Liebler	204931US-20	1234

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EXAMINER

SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/877,182	Applicant(s) LIEBLER ET AL.	
	Examiner Arlen Soderquist	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10, 13, 15-17, 23, 26, 28-31, 33-37, 40, 43, 44 and 46-48 is/are rejected.
- 7) ☒ Claim(s) 5-9, 11, 14, 18-22, 24, 25, 27, 32, 38, 39, 41, 42 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1743

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 10, 13, 15-17, 23, 26, 28-31, 33-37, 40, 44 and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Wade. In the paper Wade teaches the development of algorithms for automated elucidation of spectral feature/substructure relationships in tandem mass spectrometry. A pattern-recognition artificial-intelligence program, referred to as MAPS (method for analyzing patterns in spectra), is described for the identification of relationships that exist between the presence of substructures in molecules and the characteristic features they produce in mass spectrometry (MS) and tandem MS data. The MAPS algorithm discovers these relationships by intelligent analysis of a database of MS and tandem MS spectra. The relationships found are expressed as rules, which may then be used to identify characterized substructures in "unknowns". No prior knowledge of fragmentation pathways or rearrangements is assumed in the rule-generation process. While MAPS currently uses MS and tandem MS data, the approach (and much of the software) is equally suited to multiple-stage mass spectrometric data. In the last paragraph of page 169, Wade teaches that some common fragment ions and their assumed neutral losses that are based on the difference between two peaks have been recognized as fairly specific indicators of certain substructures and are in use in spectral interpretation. In the third paragraph of page 171, Wade describes work done by Cross in which individual daughter spectra were correlated with specific substructures. The presence of these substructures was then determined by matching the daughter spectra of unknowns against the reference spectra. In the paragraph bridging pages 173-174 the processing of data is explained including extraction of relevant data and verification that the spectra are in the proper format and error-free. Pages 174-178 teach how the rules that govern the searches in the unknown spectra are established. This includes m/z values seen in conventional and daughter scans, neutral losses, parent-to-daughter transitions and the presence of a molecular ion. Pages 178-180 teach how unknown spectra are evaluated using these rules. With respect to the steps of claim 1, the first three steps are covered as the computer uses the established rules to look for a substructure

Art Unit: 1743

in unknown spectra. The final step is taught in the first paragraph under the "Validation of substructure identification rules" subheading on page 180 in the use of a match value or a percentage of the features in a rule that are met by the compound. Also see table 2 showing how changing the match value changes the number of unknown compounds that the computer returns as having a particular substructure.

3. Claims 1-2, 10, 12-13, 28-31, 33-35, 37, 40, 43-44 and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Kwiatkowski. In the paper Kwiatkowski presents a combined forward-reverse library search system (routine) for the identification of low-resolution mass spectra. The routine requires binary-coded spectra. Masses and peak intensities are used for spectral comparison. On the basis of 3 possible search strategies, this routine is adaptable to analytical problems. The program was tested for 25,000 spectra from the ISAS, MSDC and EPA mass spectra libraries. The program is written completely in FORTRAN IV. In this paper either the unknown spectra or the library spectra are used as the spectral characteristics to mine. The routine produces a match factor (page 220, last full paragraph) that is used to indicate the similarity between the two spectra being compared. See table 4 for an example of the results of the search.

4. Claims 5-9, 11, 14, 18-22, 24-25, 27, 32, 38-39, 41-42 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The art of record fails to teach or fairly suggest these limitations in combination with the elements of the claims from which they depend.

5. Applicant's arguments filed August 16, 2005 have been fully considered but they are not persuasive. Relative to applicant's invention identifying data that displays specific characteristics defined by the user, examiner responds as follows. First the rejected claims do not limit how specific characteristics are defined by the user. For example, in claim 1, step a) could include looking a methyl group, a portion of a known molecule or the complete known molecule. Step b) would then include defining the peaks associated with that particular structure. This could include the peaks for a methyl group, differences between peaks in the spectrum that would indicate a loss of a methyl group or all of the peaks in the known molecule. Step c) would include searching for the particular peaks, daughter spectra or peak differences, in the unknown

Art Unit: 1743

spectrum. Step d) would then include calculating a score or probability that the methyl group or part of a known molecule was present in the unknown structure or that the unknown was the known molecule. In this way identifying a spectrum against a database of known spectra in the classical sense is within the scope of the instant claims. Also, identifying groups or portions of molecules from a list of possible groups is also within the scope of the claims. Since there is no limitation on how the spectral characteristics are specified, the first step could be an interactive process, a list of spectral characteristics to look for or a database of known structures to compare against. Second the claims are not limited to a particular type of unknown – peptide forms. In this way the Wade and Kwiatkowski disclosures anticipate the instantly rejected claim scope.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

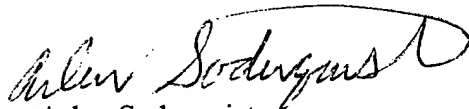
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art is directed to methods, apparatus and computer programs that are similar to the Wade or Kwiatkowski reference or that show that various features are a part of the mass spectra of proteins and peptides.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script, reading "Arlen Soderquist".

Arlen Soderquist
ARLEN SODERQUIST
PRIMARY EXAMINER